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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,242	09/19/2006	Fumio Kamiyama	3019.014USU	7413

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EXAMINER	
ORWIG, KEVIN S	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,242	KAMIYAMA ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *Sep. 19, 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/27/06, 12/18/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-7 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Election/Restrictions

Applicants' election of Group I (claims 1-7) in the reply filed on Oct. 27, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 8-10 have been cancelled.

Specification

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 365(c), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an

international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the

information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Applicants are advised that priority applications cannot be incorporated by reference after the original filing of the instant application. See United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003) "Benefit of Prior-Filed Application" (see Part VII).

Abstract

The abstract of the disclosure is objected to because the abstract does not conform to current USPTO guidelines for the preparation of patent abstracts. Currently, the abstract is too long. Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The language should be clear and concise and should not repeat information given in the

title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

A new abstract (150 words or less) is required that is sufficiently detailed as to provide general information about the precise nature of the invention to which the claims are directed. New matter is not permitted in the revised abstract. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation "...and a primary amino group and/or carboxyhydrazine group on a side chain" in claims 1 and dependent claims 2-7 is indefinite. It is not clear where the primary amino group and/or carboxyhydrazine group is intended to be located. Must one of these two functional groups be present on the (meth)acrylic acid, on another constituent component, or both? This issue is not resolved in the specification, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, the claims are indefinite.

Priority

Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the Japanese application was filed with the USPTO on Sep. 19, 2006.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7are rejected under 35 U.S.C. 103(a) as being unpatentable over TERAHARA (U.S. 2006/0110433; Filed Aug. 7, 2003) in view of KAMIYAMA (WO 00/44846; Published Aug. 3, 2000).

1. Terahara discloses a transdermal patch comprising an adhesive agent which comprises acrylic polymers that have no substantial carboxyl groups (abstract). The adhesive taught by Terahara comprises a crosslinkable acrylic copolymer of polyacrylate and diacetone acrylamide (i.e. copolymer A of instant claim 1) (paragraphs [0013], [0023], and [0025]; claim 5) and a basic nitrogen-containing acrylic copolymer wherein the nitrogen may be a primary amino group (i.e. copolymer B of instant claim 1) (paragraphs [0010], [0011], [0046], and [0047]). Terahara teaches that the acrylic polymer (i.e. copolymer A) comprises (meth)acrylic acid esters as the main constituents of the acrylic polymer (paragraph [0023]) and teaches that it is preferred to copolymerize these main chain constituents with another monomer, such as diacetone acrylamide (paragraph [0024]; claim 5).

2. Terahara teaches that the ratio of the adhesive base to the nitrogen-containing copolymer (i.e. copolymer B) is from 9:1 to 1:1 and teaches that the nitrogen-containing copolymer is present in a range of 1-30% by weight relative to the total amount of the adhesive base (paragraphs [0052]). The adhesive base of Terahara includes both the acrylic copolymer and a rubber copolymer which are themselves present in a ratio of 1:1 to 1:9 (paragraph [0042]). Thus, the ranges taught by Terahara encompass the

instantly claimed amount of copolymer B. For example, when the adhesive base is composed of a 1:1 mixture (i.e. 100 parts each) of the acrylic and rubber polymers, and the total of these two copolymers (i.e. the adhesive base) is in a ratio of 9:1 with the nitrogen-containing copolymer, the nitrogen-containing copolymer is present at a level of 22.2 parts by weight.

3. Terahara is silent as to the specific diacetone acrylamide content of the acrylic copolymer in their invention, and do not explicitly teach that the nitrogen-containing copolymer contains no free carboxyl groups.

4. However, Terahara teaches that polymers containing carboxyl groups are undesirable for applications to human skin because these types of polymers do not have optimal compatibility with skin and that acrylic polymers containing no substantial carboxyl groups can be used to solve this problem (paragraphs [0007], [0008], [0019], [0023]; claim 1). Terahara further teaches that it is preferable to decrease the carboxyl group content of the acrylic polymers as much as possible (paragraph [0030]). In light of this teaching, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to remove the free carboxyl groups from all polymers in the adhesive composition by any means known in the art, to provide a more skin-compatible adhesive as taught by Terahara.

5. Furthermore, Kamiyama discloses a skin-compatible adhesive composition for transdermal patches comprising crosslinked acrylic copolymers (abstract; page 8, 3rd paragraph). Kamiyama teaches that where the adhesive is for use in a transdermal patch, it is preferred that a polar monomer be copolymerized with the alkyl acrylate main

constituent component. Diacetone acrylamide is such a preferred monomer component because it enables more advantageous drug loading (page 8, last paragraph to page 9, 2nd paragraph). Kamiyama teaches that the diacetone acrylamide should be present in no more than 50% w/w because higher amounts can lead to reduced adhesion (page 9, 3rd paragraph). Kamiyama also teaches that a particularly preferred embodiment of the adhesive polymer is a combination of two (meth)acrylic acid alkyl esters and diacetone acrylamide in a ratio of 4:4:3 (page 10, 2nd paragraph).

6. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include diacetone acrylamide as an essential component of the acrylic copolymer of Terahara in the range of 3-45%. It would have been routine for one of ordinary skill in the art to optimize the levels of diacetone acrylamide in the copolymer, particularly in light of Kamiyama's teaching that levels of the monomer component (e.g. diacetone acrylamide) can be manipulated to provide optimum drug retention and delivery (page 9, 2nd paragraph). Given the preferred polymer taught by Kamiyama (page 10, 2nd paragraph), it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare an adhesive polymer without carboxyl groups and having diacetone acrylamide as an essential component in the range of 3-45%. One would have been motivated to do so because Kamiyama teaches that diacetone acrylamide confers advantageous drug loading and should be present in an amount of 50% or less. Further, it is well within the skill of the ordinary artisan to optimize the levels of diacetone acrylamide as taught by Kamiyama. One would have been motivated to remove the carboxyl groups from the

acrylic copolymers included in the adhesive per Terahara's teaching that doing so improves skin compatibility. Therefore if an artisan wanted to produce a skin-compatible adhesive for a transdermal patch with high drug loading capability, one would have been motivated combine Terahara and Kamiyama and claim 1 is rendered obvious over these references.

7. Claims 2-4 are product-by-process type claims. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See MPEP § 2113. Claims 2-4 are drawn to the pressure-sensitive adhesive of claim 1 wherein copolymer B is obtained by various reaction schemes. The substance and structure of the claimed pressure sensitive adhesive is not affected by this limitation, which merely reflects processes that could be used to make the adhesive of claim 1. Since the adhesive of claim 1 may comprise *either* a primary amino group *or* a carboxyhydrazide group in copolymer B, the limitation "...copolymer B is an acrylic copolymer obtained by..." does not add patentable weight to the claim. If the product in this claim is the same as or obvious from a *product* of the prior art, the claim is unpatentable. The adhesive of claim 1 is clearly disclosed in the prior art, thus claims 2-4 are rejected as unpatentable over Terahara and Kamiyama.

8. Regarding claim 5, Terahara teaches a patch for transdermal use wherein the adhesive layer is disposed on a backing layer, which may be various types of cloth, polymers, or an aluminum sheet (paragraphs [0005], [0019], and [0020]). Thus claims 5 and 7 are rendered obvious over Terahara and Kamiyama.

9. Additionally, Terahara teaches the use of plasticizers in the adhesive of the invention. Terahara teaches that the amount of plasticizer is not particularly limited, but is preferable to be between 5-70% of the compounds in the adhesive layer (paragraphs [0063] and [0064]). Therefore the combination of Terahara and Kamiyama renders claim 6 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643